

REMARKS/ARGUMENTS

I. Status of the Claims

Claims 1-29 are pending in the instant application. Claims 24-29 are withdrawn from consideration. Claims 1-23 stand rejected under 35 U.S.C. § 102(a), 102(e) and 102(b).

II. Claim rejections

A. Rejection of Claims 1-23 under 35 U.S.C. § 102.

Claims 1-23 stand rejected under 35 U.S.C. § 102 (a) and 102(e) as allegedly being anticipated by Nadkarni et al. (U.S. 2002/0013357), published 1/31/2002; and under 35 U.S.C. § 102(b) as allegedly anticipated by Nadkarni et al. (WO 01/41761 A2).

Applicants have amended Claim 1 to include the limitation **"said pregelatinized starch selected on the basis of determination of low viscosity and/or a particle size test."** This limitation is not present in any of the art of record. Support for this limitation is found, for example, in paragraph [0015]; paragraph [0036]; and paragraphs [0043] through [0044], for example.

This limitation further clarifies that it is the selection of a sample of pregelatinized starch based upon the sample's characteristics that accomplishes the result of creating a formulation that passes pre-established dissolution rate criteria. Prior to this discovery, fully processed formulations, including the active ingredient, were tested for appropriate dissolution. This resulted in waste, because if the formulated tablet failed to meet the pre-established dissolution criteria, the lot would be discarded. The inventors of this formulation have discovered that in low water soluble compound formulations, there is a direct correlation between dissolution and the viscosity and/or particle size of the pregelatinized starch used in the formulation. It was discovered that in commercial lots of pregelatinized starch, there was variability **within** the same brand or type of starch.

Example 1, paragraphs [0081 through [0085]; and Example 2, paragraphs [0086] through [0089]; Example 3, paragraphs [0090] through [0092] and Example 4, paragraphs [0093] through [0096] demonstrate this variability. Therefore, it is not the starch that is purchased and used **without** determining the viscosity or particle size that is used in the formulation, as in the art of record, but it is the **selection** of the

pregelatinized starch, within a larger group of variable pregelatinized starch, that represents the advance realized by the present invention. None of the prior art of record, including Nadkarni et al. (U.S. 2002/0013357) and Nadkarni et al. (WO 01/41761 A2),

teach or suggest this limitation, and therefore, it is respectfully requested that the rejections under 35 U.S.C. § 102(a), 102(e) and 102(b) be withdrawn.

III. Conclusion

For all of the above reasons, reconsideration and withdrawal of the rejections under 35 U.S.C. § 102(e), 35 U.S.C. § 102(a) and 35 U.S.C. § 102(b) is respectfully requested.

If the Examiner believes a telephonic interview with Applicant's representative would aid in the prosecution of this application, the Examiner is cordially invited to contact Applicant's representative at the below listed number.

Respectfully submitted,



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